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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,517

02/11/2005

Masao Morimoto

TIP-05-1008

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IP GROUP OF DLA PIPER US LLP  
ONE LIBERTY PLACE  
1650 MARKET ST, SUITE 4900  
PHILADELPHIA, PA 19103

EXAMINER

LEESER, ERICH A

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

08/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/524,517

Applicant(s)

MORIMOTO ET AL.

Examiner

Erich A. Leeser

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 8, 12, 15-17 and 19-24 is/are rejected.
- 7) ☒ Claim(s) 4, 6, 9, 10, 13, 14 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6-22-05 and 2-11-05</u> . | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

1. Claims 1-24 are currently pending and under examination.

#### *Priority*

2. Acknowledgment is made that this application is a 371 of PCT/JP03/11204, filed on September 2, 2003, which claims foreign priority to application JAPAN 2002-260376, filed on September 2, 2003. Although the priority document submitted or transmitted in compliance with rule 17.1(a) or (b) was received by the Office on February 11, 2005, the Office has yet to receive from Applicant a certified translation of JAPAN 2002-260376.

#### *Information Disclosure Statement*

3. The references cited in the IDS, dated February 11, 2005 and June 22, 2005, are made of record.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-2, 8, 11-12 and 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The following apply. Any claim not specifically rejected is rejected if it is dependent on a rejected claim and shares the same indefiniteness.

(a) Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The chemical process is unclear because although it includes the piperazine reagent and the piperazine product, it is missing the oxycarbonyl reagent to complete the

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reaction. This rejection could be obviated by including the structure of the oxycarbonyl reagent, such as drawn in claim 2, in the body of claim 1. In addition, it is unclear at what point or step in the reaction the oxycarbonyl is used to attach to the piperazine. Clarification is required.

(b) Claim 2 is rejected because although general formula (3) includes the structure “Y,” nowhere in the claim is “Y” defined. Correction is required.

(c) In claim 8, it is unclear what Applicant intends by the last clause of the claim. Is the “nitrogen-containing aromatic compound” an impurity or byproduct or something else? Clarification is required.

(d) In claims 11 and 12, “the raw material” lacks antecedent basis because this term is not used in either of these claims or in preceding claims 1 and 7.

(e) In claim 12, it is unclear what Applicant intends by the last three lines of the claim. Specifically, Examiner is not sure if the “0.5 to 4.0 times by weight” applies to the initial “piperazine derivative,” the final “piperazine derivative,” the “racemic modification,” the “lower carboxylic acid or mineral acid,” the “solvent” or the “raw material.” Also, the Examiner is confused as to the steps involved in obtaining the final “piperazine derivative” by “optically resolving a piperazine derivative.” Clarification is required.

(f) In claims 19-24, the term “highly pure” is very unclear. How pure is “highly” pure? A reader would have to speculate as to the metes and bounds of this claim because what Applicant intends by this claim term is ambiguous. Clarification is required perhaps including a specific and concrete range.

(g) In claim 19, “the mutual solubility” lacks antecedent basis because this claim term was not previously stated in preceding independent claim 1. What does Applicant intend by

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“mutual solubility” with water in claims 19 and 20? Is this “water” the same as the subsequent “water solvent” or different in claim 19? Clarification is required.

(h) In claim 21, “2 liquid chromatography area % or less” is unclear. Does the “2” refer to the number of liquids, the type of chromatography or the size or the area? If the number of liquids, what specific liquids are they? Clarification is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5, 7, 11-12 and 15-17 are rejected under 35 USC 102(b) as being anticipated by Shafiee, et al., WO 96/12492. The reference teaches various processes of making oxycarbonyl-substituted piperazine compounds, which include instant process. Specifically, process Example 10, beginning on page 43 of the reference anticipates the aforementioned claims when R<sup>1</sup>, R<sup>3</sup> and R<sup>4</sup> are all hydrogen, R<sup>2</sup> is vii) and X is tertiary butyl. The organic solvent claim limitation is met by the solvents listed under “Materials” on page 43, at least one having 15% or less of water. Therefore, the instant claims 1-3, 5, 7, 11-12 and 15-17 are anticipated by Shafiee, et al., WO 96/12492.

***Claim Objections***

7. Claims 4, 6, 9-10, 13-14 and 18 are objected to as being dependent upon rejected independent claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

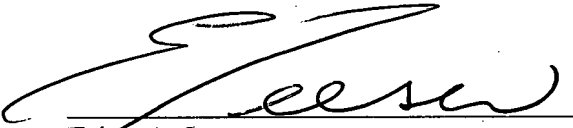
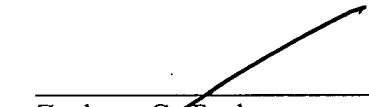
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***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
\_\_\_\_\_  
Erich A. Leeser  
Assistant Examiner  
\_\_\_\_\_  
Zachary C. Tucker  
Primary Examiner  
\_\_\_\_\_  
**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**